



August 15, 2000
Dockets Management Branch
(HFA-305)
Food and Drug Administration
5630 Fishers Lane
rm. 1061
Rockville, MD 20852

NATIONAL
FOOD
PROCESSORS
ASSOCIATION

Re: Docket No. 00D-1305; Foods: "Apple Juice, Apple Juice Concentrates, and Apple Juice Products – Adulteration with Patulin;" Draft Compliance Policy Guide; 65 Federal Register 37791; June 16, 2000.

Dear Sir or Madam:

The National Food Processors Association (NFPA) provides the following comments in support of establishment of a Compliance Policy Guide (CPG) for Patulin in apple juice, apple juice concentrates, and apple juice products as referenced above.

The National Food Processors Association (NFPA) is the principal scientific trade association representing the \$430 billion food processing industry in the United States of America. With three laboratory centers, NFPA is the leading authority on food science and safety for the food industry. For more than 90 years, the food industry has relied on NFPA for government and regulatory affairs representation, scientific research, technical services, education, communications, and crisis management.

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NFPA members support the establishment of an Action Level of 50 parts per billion (ppb) (1ppb = 1µg/kg) as a maximum limit for patulin in apple juice, apple juice concentrates, and apple juice products produced or imported into the US. The Action Level to be based on single strength apple juice or apple juice from concentrate.

NFPA members have been using a 50ppb action level maximum level for patulin in apple juice and apple juice concentrate (11.5°Brix, single strength equivalent) on a voluntary basis for several years and routinely include this requirement in purchase specifications. Product found to exceed this limit is rejected and returned to the supplier. NFPA obtained and provided this data (both accepted and rejected samples) to FDA for the Agency's review and assessment. NFPA members have expressed their concern that, without a regulatory limit, such rejected product could enter the food supply. Accordingly, in 1996, NFPA, at the request of its Juice Products Committee, sent a letter to FDA (copy attached) requesting the Agency establish a 50ppb limit for patulin in apple juice.

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NFPA members also support establishment of the 50ppb limit for patulin at the international level through the Codex Committee on Food Additives and Contaminants (CCFAC) of the Codex Alimentarius Commission. A proposal to adopt the 50ppb limit was sent forward by CCFAC at step 8 in the Codex approval process. The document has been sent to the Commission for final approval as a Codex standard in 2001. If approved by the Commission the Codex limit will serve as an international standard for patulin for use in World Trade Organization (WTO) deliberations. NFPA requests that FDA, through the US Codex Delegation, continue to support the 50ppb limit at the Codex Alimentarius Commission meeting in July 2001.

The 50ppb limit for patulin proposed by FDA is within the analytical capability of the method of analysis also proposed by the agency. The current method is listed in the Official Methods of Analysis of the Association of Official Analytical Chemists (AOAC), Sixteenth Edition, section 995.10-Patulin in Apple Juice, liquid chromatographic method and was adopted in 1995 (published in JAOAC 79(2): 452-455, 1996). The method has a lower quantification limit of $20 \text{ ppb} \pm 10 \text{ ppb}$ and a lower detection limit of $\approx 5 \text{ ppb}$. To account for the variability of the method industry members indicate that any lot found to contain 40-49 ppb would be resampled and retested. If the second test is at or above 50 ppb the product will be rejected.

NFPA agrees with FDA's conclusion as stated in the draft safety assessment document that:

"The information presented in this paper supports an $50 \mu\text{g/kg}$ action level for patulin in apple juice, apple juice concentrates, and apple juice products based on the level found or calculated to be found in single strength apple juice or in the single strength apple juice component of the product."

Accordingly, NFPA supports the FDA proposal to establish a Compliance Policy Guide with a 50ppb limit for patulin in apple juice and single strength apple juice from concentrate.

Thank you for providing this opportunity to comment on the Compliance Policy Guide.

Sincerely,

A handwritten signature in black ink, appearing to read 'Allen Matthys', with a stylized flourish at the end.

Allen Matthys, Ph.D.
Vice President
Regulatory Affairs



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November 1, 1996

Dr. Terry Troxell

Division of Enforcement and Programs Policy (HFS-305)

Center for Food Safety and Applied Nutrition

Food and Drug Administration

200 C Street SW

Washington, DC 20204

Dear Dr. Troxell:

The National Food Processors Association requests the Center for Food Safety and Applied Nutrition, Food and Drug Administration issue guidelines establishing a maximum level for patulin of 50 µg/kg in apple juice and single strength apple juice from concentrate to assure the product is prepared from good quality fruit.

Patulin is produced by various molds which infect apples. If moldy apples are used to produce apple juice, patulin is likely to be present in the juice. Its presence serves as a good indicator of the quality of the fruit used to produce the juice. Patulin levels in excess of 50 µg/kg are more likely to be associated with excessively moldy fruit. Because patulin is not destroyed by heat treatments such as pasteurization, NFPA is requesting the Food and Drug Administration to establish a guideline or defect action level of 50 µg/kg as a maximum limit for patulin in apple juice and single strength equivalent apple juice from concentrate as an ingredient in food intended for human consumption.

Establishment of a 50 µg/kg limit for patulin in apple juice would harmonize U.S. requirements with our trading partners. Many countries¹, including Austria, Belgium, France, Norway, Sweden, and Switzerland, have established a maximum level of 50 µg/kg for patulin in apple juice and apple juice prepared from concentrated apple juice to be used as an ingredient in food for human consumption. Levels above this limit are viewed as having been prepared from excessively moldy fruit. To assure that their products are prepared from juice obtained from sound fruit, many U.S. companies which manufacture and/or purchase apple juice and apple juice concentrate include in their product

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¹ Van Egmond, H.P., Current situation of regulations for mycotoxins. Overview of tolerances and status of standard methods of sampling and analysis, Food Additives and Contaminants, 1989. Vol. 6, No. 2, 139-188.

specifications a maximum limit for patulin of 50 µg/kg based on single strength equivalent apple juice from concentrate.

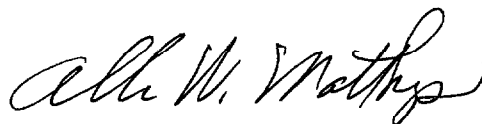
Because the U.S. FDA has no defect action level or guidance limit for patulin in apple juice and apple juice concentrate, NFPA members report rejecting shipments of imported apple concentrate which exceed the 50 µg/kg limit established in their company specifications. They speculate this product is being diverted to the U.S. from those countries which have established limits or guidance levels for patulin.

In order to assure that apple juice sold in the U.S. is prepared from sound apples, NFPA requests the Agency establish an action level of 50 µg/kg for patulin in apple juice and single strength equivalent apple juice from concentrate (11.5° Brix). Apple juice containing in excess of this amount would be considered as being prepared from excessively moldy fruit and therefore adulterated under section 402(a)(3) of the Federal Food, Drug, and Cosmetic Act.

We encourage FDA to move expeditiously in establishing this guideline.

Thank you for your assistance. If you have any questions please contact me.

Sincerely,

A handwritten signature in black ink, reading "Allen W. Matthys". The signature is fluid and cursive, with the first name "Allen" and last name "Matthys" clearly legible.

Allen W. Matthys, Ph.D.
Vice President
Technical Regulatory Affairs



NFPA

The Food Safety People

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